



EXOPULSE

User Manual English

This user manual (version 1.6 EN) was produced by EXONEURAL NETWORK AB and applies to EXOPULSE Mollii Suit.

The operating instructions are valid from 03-05-2021.

Firmware version: 1.3x

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**1. EIGHT-STEP INSTRUCTION
ON HOW TO USE
EXOPULSE MOLLII SUIT**

STEP
1

READ THE INTENDED USE AND SAFETY INSTRUCTIONS CAREFULLY

EXOPULSE Mollii Suit is a personal assistive medical device which is used for low energy whole body transcutaneous electrical stimulation - 20 Volt and 20 Hz. It is composed of a control unit, a jacket and a trouser, with 58 embedded electrodes, in direct contact with the skin. The suit can be used by children or adults and comes in sizes starting from 104 cm up to 5XL men and women. It is prescribed by a health-care practitioner based on a clinical assessment. EXOPULSE Mollii Suit is used for neurological conditions such as chronic pain, stroke, multiple sclerosis, cerebral palsy or spinal cord injuries. It is intended to be used for 60 minutes every other day, unless otherwise specified by your healthcare provider, in the home environment or in a health care facility setting.

INTENDED USE

The EXOPULSE Mollii Suit consists of the EXOPULSE Control Unit and EXOPULSE Body Garments (Jacket and Pants).

EXOPULSE Body Garments (Jacket and Pants)

The EXOPULSE Body Garments (Jacket and Pants) is a suit with embedded electrodes, conductive wires and connectors to a detachable control unit, who's intended purpose is to transmit electric pulses from the control unit to key nerves and corresponding muscle groups throughout the body.

EXOPULSE Control Unit

The EXOPULSE Control Unit is a battery powered electrical device which sends low energy electric pulses through connectors to the EXOPULSE Body Garments which in turn transmits the pulses from the connectors to key nerves and corresponding muscle groups throughout the body.

The intended use of EXOPULSE Mollii Suit is:

- Relaxation of spastic muscles
- Maintaining or increasing range of motion
- Activation and re-education of muscles
- Retardation or prevention of disuse atrophy
- Increasing local blood circulation
- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment for post-surgical pain

EXOPULSE Mollii Suit is for use in the home environment.

MODE OF ACTION

EXOPULSE Mollii Suit is used for activation of weak muscles or relaxation of spastic muscles mediated by a physiological reflex mechanism referred to as reciprocal inhibition. By sending an electrical signal to an antagonistic muscle, the spastic muscle will subsequently relax. EXOPULSE Mollii Suit is also used for management of chronic pain, mediated selectively stimulating the nerve fibers carrying non-pain sensory stimuli from a specific region, to reduce the effect of pain signals.

CONTRAINDICATIONS

Do not use:

- If the user has implanted electronic medical devices or equipment which can be disrupted by magnets, for example, shunts
- together with electronic life-support equipment or high-frequency operation equipment
- together with ECG-equipment

There is a risk of EXOPULSE Mollii Suit disturbing the function of the above mentioned types of equipment.

Stimulation should not be applied:

- over swollen, infected, or inflamed areas or skin eruptions e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- transcranially

WARNINGS - Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

EXOPULSE Mollii Suit may only be used by, or under the supervision of, a person who has read and understood the entire user manual.

Do not use EXOPULSE Mollii Suit without consulting a doctor in connection with:

- Cardiovascular diseases or other types of related conditions:
- Malignancy (cancer)
- Infectious diseases
- Fever
- Epilepsy
- Skin disease, rashes or other skin problems
- Usage together with another medical device.

Usage in connection with the above can expose the user to unnecessary risk, and is

therefore at the user's own risk. Always consult a doctor.

EXOPULSE Mollii Suit should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

EXOPULSE Mollii Suit should not be serviced while in use.

Do not modify EXOPULSE Mollii Suit without authorization of the manufacturer.

Do not use EXOPULSE Mollii Suit outdoors, in wet rooms, in direct sunlight, or in connection with flammable materials/liquids. Keep away from dusty, damp and bright environments to avoid damage or harm to EXOPULSE Mollii Suit.

Do not use EXOPULSE Mollii Suit near a magnetic resonance imager.

CAUTIONS - Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

Caution should be used in the presence of the following:

- when there is tendency to hemorrhage following acute trauma of fracture, following recent surgical procedures when muscle contraction may disrupt the healing process,
- over the menstruating or pregnant uterus, and
- over areas of the skin which lack normal sensation.

Use of this equipment adjacent to, stacked with or interconnected to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of EXOPULSE Mollii Suit could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable radio frequency communications equipment (including cell phones, computers and peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Therapeutic equipment that transmits micro-waves or short waves should be used no closer than 1 m (33 inches) to any part of the equipment. Otherwise, this could result in the degradation of the performance of the equipment.

Remove all batteries if EXOPULSE Mollii Suit is not going to be used for three weeks

or more, to avoid the risk of battery leakage and corrosion.

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

EXOPULSE Mollii Suit is for use solely by the user for whom it is adapted.

Take care when children and pets are present to avoid damage or harm to EXOPULSE Mollii Suit.

Avoid contact with all substances and chemicals found in the home environment, except for water used for washing or body lotion used to moisture the skin.

Spilling liquid on EXOPULSE Mollii Suit can cause discomfort. Drinks and liquids should be avoided during use. The garment should not be used when the garment or control unit is wet or damped and should immediately be turned off in such circumstances.

Ensure that the magnetic couplings are correctly positioned (see STEP 5.)

Ensure that the magnetic coupling (in garment and control unit) does not come into contact with devices that can be destroyed by magnets.

Jewellery, accessories (in contact with the garment) and underwear with metal buckles should not be used together with EXOPULSE Mollii Suit.

Never insert objects or tools under the garment.

Do not use EXOPULSE Mollii Suit if the control unit has visible marks or is damaged. Always check that EXOPULSE Mollii Suit is intact, dry and clean before use, and make sure to wash the garment before using it the first time.

Wearing EXOPULSE Mollii Suit can cause sweating and dehydration, especially when worn in humid and warm conditions. Drink sufficient fluids in order to avoid dehydration.

Take care when using EXOPULSE Mollii Suit. Bear in mind that, for example, balance may be affected. Do not undertake demanding or heavy physical exercise when using EXOPULSE Mollii Suit.

Electrotherapy can make the user tired and drowsy. Do not undertake activities

which require intense concentration if feeling tired or drowsy.
Follow the instructions for cleaning the garment and electrodes in STEP 8.

Regular contact with electrodes can irritate or chafe the skin. It is therefore particularly important to maintain good hygiene and to ensure:

- That the electrodes are clean and in good contact with the skin.
- To wash the skin every day with soap and water.
- To moisturize the skin with unscented skin lotion.
- Never to use EXOPULSE Mollii Suit if there the skin is dry, sore, irritated or injured.

The magnetic arms on the control unit must be handled with care, and:

- must not be forcefully removed, but lifted from their respective magnetic coupling, one at the time,
- must not be twisted when connected to the suit, and
- must not be bent to from sharp angles, but instead must allow ample curves.


The magnetic arms should be tested for wear and tear once per year, and replaced if faulty. In addition to that, in case of loosened components and/or if effect is absent and/or decreased, please contact your local EXONEURAL NETWORK AB partner. The replacement must only be done by an approved personell, and will be covered by the product warranty, provided that the product has been handled according to instructions contained herein.

Do not use carbon-zinc AAA batteries as they do not last very long and they may leak acid into the EXOPULSE Mollii Suit device.

ADVERSE REACTIONS

Skin irritation and burns beneath the electrodes have been reported with the use of transcutan electrical stimulators.

SUPPORT, ACCIDENTS, INJURIES OR INCIDENTS

Contact EXONEURAL NETWORK AB if an accident, incident, or injury occurs, or if this symbol shows up on the screen: 

EXONEURAL NETWORK AB, Svärdvägen 11D, 182 33 Danderyd, Sweden
Phone: +46 (0)8 410 277 01, e-mail: info@exopulse.com

For service and repair, or if you need support with your EXOPULSE Mollii Suit, please contact your local EXONEURAL NETWORK AB partner.

In case a serious incident report to your competent authority as well.

**STEP
2**

CHECK THAT THE SET IS COMPLETE

EXOPULSE Mollii Suit
jacket*



EXOPULSE Mollii Suit
control unit supplied
with a belt*



EXOPULSE Mollii Suit
trousers*



Laundry bag x2



Protective box for the
control unit



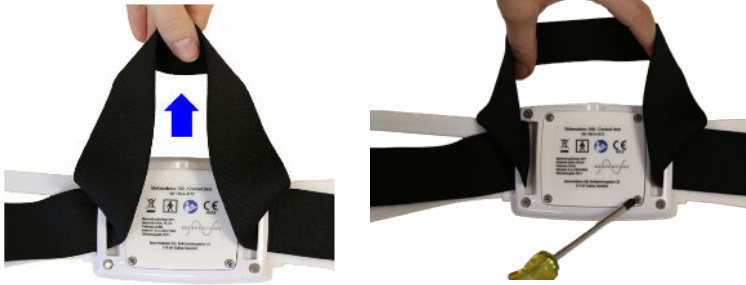
** Note: Jacket, trousers and control unit have unique item numbers. .*

STEP 3

Alkaline AAA batteries are acceptable for use.

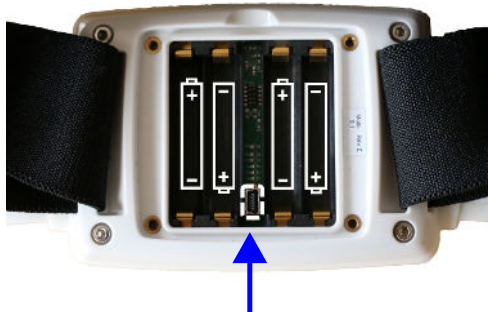
OPEN BATTERY COVER

Place the control unit with the screen facing down. Pull the belt away to uncover the battery hatch. Use a crosshead screwdriver to undo the 4 screws on the rear of the control unit and remove the rear cover.



INSERT BATTERIES

Insert 4 x AAA batteries according to the the polarities indicated in each battery socket. Always check that + and – poles are turned in the right direction, using the mini USB as a reference point as indicated below:



MINI USB SHOULD BE FACING DOWN

CLOSE BATTERY COVER

Check that no screws or external items have been left behind before replacing the battery cover in the directions indicated in the battery socket. Screw the cover on firmly using a screwdriver.

CHECK THE BATTERY LEVEL

Turn the control unit on by pressing the ON button. Check the battery level:



Battery full



Battery half full



Battery low.
Replace batteries

STEP 4

DRESSING UP

FAVOR NARROW UNDERWEAR

Ensure to moisturize your skin with unscented lotion. Choose a narrow pair of underwear to make sure the underwear is not covering the electrodes on the inside of the garment. Underwear should be adjusted if they are in the way of the electrodes.



OPEN ALL THE TROUSERS' ZIPPERS BEFORE DRESSING UP

PUT THE TROUSERS ON

ADJUST THE KNEE-CAP PLACEMENT

Ensure that the seam is above the knee.



CLOSE THE TROUSERS' ZIPPERS

CHECK THAT THE ELECTRODES ARE IN CONTACT WITH THE SKIN

OPEN ALL THE JACKET'S ZIPPERS

PUT THE JACKET ON

ENSURE THE JACKET IS OVER THE PANTS

The jacket should be outside the trousers. Snap the jacket to the trousers with the buttons.

CLOSE THE JACKET'S ZIPPERS



ADJUST THE FOREARMS PLACEMENT

Make sure that the zippers are on the outside of the forearm and form a straight line between the elbow and the little finger as indicated below:



**STEP
5**

INSTALL THE CONTROL UNIT

POSITION THE CONTROL UNIT

Place the control unit on the belly above the hipline and below the waistline with the display facing away from the belly as indicated below:



CLICK THE BELT AROUND THE WAIST

Click the belt on by vertically sliding the two parts together.



ADJUST THE LENGTH OF THE BELT



RECHECK THAT THE CONTROL UNIT IS ON

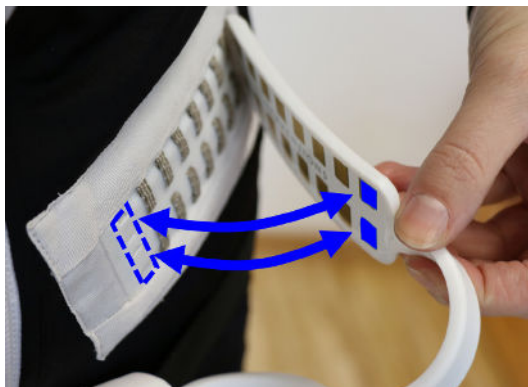
Recheck that the control unit is on. If not, press the ON button.



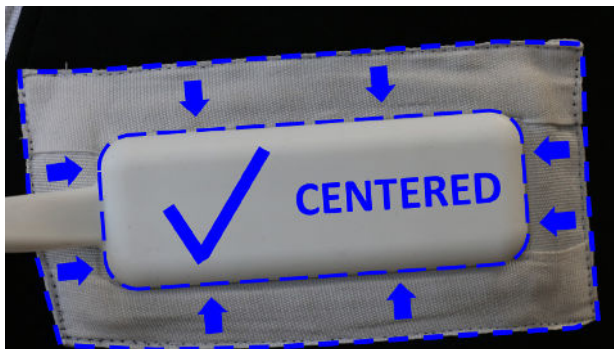
CAREFULLY CONNECT THE MAGNETIC ARMS

Place the upper left magnetic arm carefully on the upper left connector. If you are experiencing magnetic repulsing, then you are placing the wrong magnetic arm. Proceed with placing the upper right magnetic arm on the upper right magnetic connector, and the lower left magnetic arm on the lower left connector, and finally the lower right magnetic arm on the lower right connector.

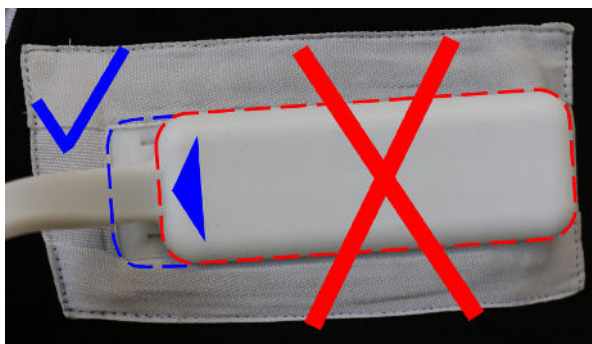
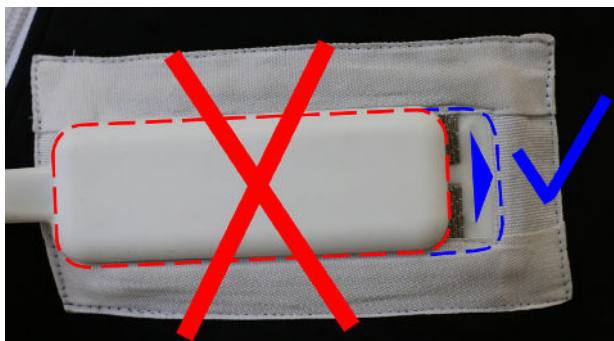
Make sure each magnetic arm is correct positioned on each connector, as indicated below.



Correct position:



Incorrect positions:



STEP
6

START A 60-MINUTE EXOPULSE MOLLII SUIT SESSION

START A 60-MINUTE SESSION

Press PLAY/PAUSE button once.



The display shows **PLAY** and the remaining time counting down from 60 minutes.



If necessary: **PAUSE** by pressing PLAY/PAUSE once. The display then shows:



Press PLAY/PAUSE again to continue the session.

DURING USE

While using EXOPULSE Mollii Suit, you can remain still, move around or exercise. Check that each magnetic arm is in the correct position, when moving around. If not, make sure to reposition it correctly.

EXOPULSE Mollii Suit should not be serviced while in use.

STEP
7

END THE MOLLII SESSION

TURN OFF THE CONTROL UNIT AND REMOVE IT

Turn off the control unit by pressing the ON/OFF button. Remove the control unit carefully, one magnetic coupling at a time, making sure not to pull or twist the magnetic arms. Always place the control unit back into the protective box.

OPEN ZIPPERS AND UNDRRESS

STEP 8

CLEANING, STORAGE AND SERVICE LIFE

REGULAR CLEANING

Rinse the garment in cold water or, wipe off the electrodes using wet wipes. Clean the control unit, magnetic arms and connectors at least every other month, using a lightly dampened cloth with no detergent. **Do not immerse the control unit in water.**

WASHING INSTRUCTIONS

The garment can be hand or machine washed at 40°C/104°F, using delicate wash without softener. Wash regularly (at least once every other month) to keep fabric and electrodes clean. The control unit must be disconnected from the suit before washing. Wash the garments separately in the two laundry bags supplied. Do not tumble dry or iron.

OPERATING

EXOPULSE Mollii Suit should be operated indoors under the following conditions:

- **Temperature** 5 to 42°C
- **Humidity:** 15% to 90% relative humidity
- **Altitude:** 1,060 hPa to 700 hPa (10,000 ft to -1250 ft)
- Avoid dusty, damp and bright environments

If EXOPULSE Mollii Suit has been exposed to temperatures higher or lower than the operation temperature, let the device warm up/cool down for at least one hour before use.

TRANSPORTATION AND STORAGE

Temperature: -25 to 70°C

Humidity: 15% to 90% relative humidity

Store the EXOPULSE Mollii Suit control unit in the protective box

WARRANTY AND SERVICE LIFE

EXOPULSE Control Unit is guaranteed for 2 years of regular use under the condition prescribed herein.

EXOPULSE Body Garments are guaranteed to last for 25 machine washes or 2 years of regular use under the condition prescribed herein.


Use over and above this time, or outside the prescribed conditions, is not covered by the warranties of EXONEURAL NETWORK AB.

The service life of EXOPULSE Mollii Suit is 4 years.

DISPOSAL

Please return EXOPULSE Mollii Suit to EXONEURAL NETWORK AB for disposal. Please handle used batteries in accordance with the WEEE Directive 2012/19/EU.

2. Trouble Shooting Section

Problem	Possible causes	Solution
No display	Low batteries OR Batteries inserted incor- rectly	Replace batteries OR Check instructions in Section 1 STEP 3
Display showing the symbol 	The control unit is unpro- grammed	Contact EXONEURAL NET- WORK AB or your local reseller
Sudden change in sensation OR Shifting/decreas- ing sensation during use	Incorrect position of mag- netic arms on the connec- tors OR Electrodes are not in good contact with the skin	Verify battery level and check installation of control unit and adjust suit according to instructions in Section 1 STEP 4 and STEP 5.
The skin turns red or the skin feels irritated	Dry skin or electrodes are not in good contact with the skin	Clean and moisturize the skin regularly as well as check installation of control unit and adjust suit according to instructions in Section 1 STEP 4 and STEP 5.

3. Reporting faults and accidents

If an accident, incident or injury occurs, immediately contact EXONEURAL NETWORK AB. Faulty equipment must not be used.

Immediately contact:

EXONEURAL NETWORK AB
Svärdvägen 11D
182 33 Danderyd
Sweden
Phone number: +46 (0)8 410 277 01
e-mail: info@exopulse.com

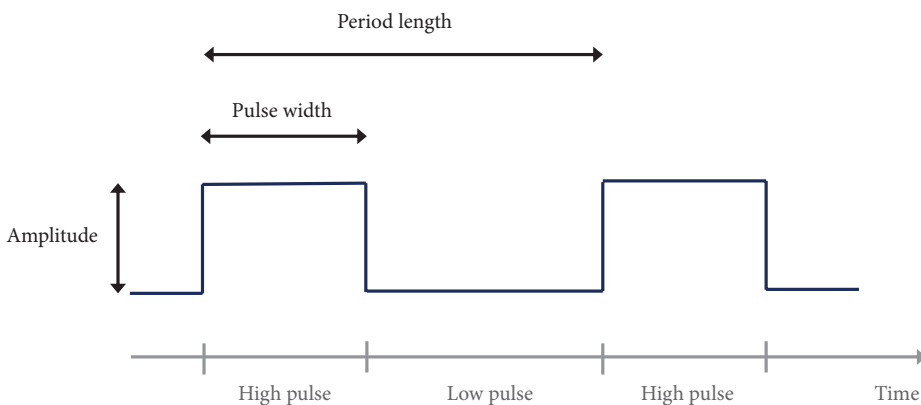
4. About electrical nerve and muscle stimulation

EXOPULSE Mollii Suit generates 2 milliamp pulses (into 0-10,000 Ohms) with the following parameters:

- Pulse width: variable between 25 and 170 μs
- Length of period: 50 ms
- Maximum amplitude: 20 V

Each EXOPULSE Mollii Suit is customized when it is prescribed. Depending on diagnosis and manual examination of the patient, the prescriber decides which muscles are to be stimulated and with which pulse parameter setting. The user cannot change parameter settings and/or which muscles are to be stimulated.

On every start and continuation from pause mode, the pulse width is increased by up to 5 μs every 5 seconds from 25 μs until the preset pulse width is reached.



5. Technical Description

ELECTRICAL STIMULATION

EXOPULSE Mollii Suit is a multi-channel full-body suit with a low energy electrical stimulation – 20 Volt and 20 Hz. It is composed of a control unit, a jacket and a trouser, with 58 embedded electrodes, in direct contact with the skin, and pre-positioned to stimulate 40 key muscle groups.

SIZES

The suit comes in 37 sizes, starting from 104 cm up to 5XL woman and man.

PROGRAMMING OF THE CONTROL UNIT

A trained medical staff pre-programs which nerves/muscles to be stimulated based on a clinical assessment of the user. The stimulation program is thus specific to each user. The operator or user can then start/pause/stop the pre-programmed session, but cannot change which nerves/muscles should be stimulated and with which intensity.

APPLIED PARTS

The EXOPULSE Mollii Suit body suit is a type BF applied part. The EXOPULSE Mollii Suit control unit is an accessible part.

SHELF LIFE

The shelf life of the garment is 2 years and the shelf life of the control unit is 3 years.

MATERIALS

The materials in EXOPULSE Mollii Suit are biocompatible and tested according to ISO 10993-1 for carcinogens, sensitivity and irritation.

6. Table Data and Standards

EXOPULSE Mollii Control Unit is CE-labelled, and thereby complies with the directive concerning medical devices (MDD 93/42/EEC).























EXOPULSE Body Garments are CE-labelled, and thereby complies with the regulation (EU) 2017/745.















In order to meet the requirements, EXONEURAL NETWORK AB has voluntarily chosen to fulfil

- EN ISO 14971
- IEC 60601-1
- ISO 10993-1
- ISO 13485
- IEC 60601-1-2
- IEC 60601-1-6
- IEC 60601-1-11
- IEC 60529 (IP22)
- IEC 62304
- ISTA 2A

Emissions test	IEC 60601-1-2 test level	Conformity
RF-emissions CISPR 11	Group 1, Class B	Group 1, Class B
Immunity test	IEC 60601-1-2 test level	Conformity
Electrostatic dis- charge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
Conducted RF IEC 61000-4-6	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 1 kHz and 6 Vrms for ISM frequencies between 150kHz-80MHz, and 6 Vrms for Amateur freq.	3V rms 150kHz - 80 MHz, 80% amplitude modulation at 1 kHz and 6 Vrms for ISM frequencies between 150kHz-80MHz, and 6 Vrms for Amateur freq.
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2,7GHz	10 V/m 80MHz to 2,7GHz
Radiated RF IEC 61000-4-3 Table 9 Wireless Fre- quencies	80-2700MHz :3 V/m ordinary, 10V/m home healthcare, 80% AM, 1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz	80-2700MHz :3 V/m ordinary, 10V/m home healthcare, 80% AM, 1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz

7. Symbols

	Button: ON/OFF. Turns the control unit on and off respectively		EXOPULSE Control Unit: declaration of conformity according to the Council Directive 93/42/EEC concerning medical devices. 0413 is the identification number for the notified body.
	Button: PLAY/PAUSE		EXOPULSE Body Garments: declaration of conformity according to the Regulation (EU) 2017/745.
	Display: If this symbol is visible in the display, the control unit is in PLAY mode		Symbol: Machine wash 40° C, delicate wash. Do not use fabric softener
	Display: If this symbol is visible in the display, the control unit is in PAUSE mode		Dry flat
	Display: Product defect – do not use the product! Contact EXONEURAL NETWORK AB if this symbol is displayed		Do not dry-clean
	Display: Battery indicator Battery full		Do not tumble-dry
	Display: Battery indicator Battery low. Replace batteries		Do not iron
	This product is labelled according to EU Directive 2002/96/EC (WEEE). The symbol means that the product must not be disposed of as domestic waste, but in a dedicated site for recovery and reuse of electronics and electrical waste.		Do not bleach
	Type BF applied parts.		Do not wring out when drying
	Read the entire user manual prior to using EXOPULSE Mollii Suit		Warning
	Temperature range		Quantity

	Device is only for use by prescription		Catalog/re-order part number
	Fragile		Date of manufacture YYYY-MM-DD
	Keep dry		Serial number
	Manufacturer		Ingress Protection Drip-proof
	Unique Device Identifier		Altitude/pressure range
	Relative humidity range		Do not use device if packing is damaged
	Device is not MRI compatible		Medical device

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